K091662

Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: _____ ." (applicant leave blank)

JUL 30 2009

Premarket Notification [510(k)] Summary

[(a)(1)]. The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared :

Submitter's name :	ZHANGJIAGANG FENGYUAN PLASTIC PRODUCTS CO.,LTD
Submitter's address :	Hengjing Village Tangqiao Town Zhang Jia Gang Jiangsu,215615,China
Phone number :	(86) 512-68416802
Fax number :	(86) 512-68416685
Name of contact person:	Mr. Yu Bang Ting
Date the summary was prepared:	May.26.2009

[(a)(2)]. The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Device Name:	Powdered Vinyl Patient Examination Gloves, Clear (Non-colored)
Proprietary/Trade name:	Powdered Vinyl Patient Examination Gloves Other clients private labeling
Common Name:	Patient examination glove
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital (80)
Product Code:	LYZ

[(a)(3)]. An identification of the legally marketed device to which your firm is claiming substantial equivalence .

Class I* powdered vinyl patient examination gloves, Clear (Non-colored) that meets all of the requirements of ASTM standard D 5250-06.

Predicate device : FUGUAN (Brand) Powdered Vinyl Patient Examination Gloves, Shijiazhuang Fuguan Plastic Products Co., Ltd.. K032907.

[(a)(4)] A description of the device

Device Description : powdered vinyl patient examination gloves, Clear (Non-colored) that meets all of the requirements of ASTM standard D 5250-06.

[(a)(5)] The summary describes the intended use of the device

Device Intended Use: powdered vinyl patient examination glove, Clear (Non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

[(a)(6)] A summary of the technological characteristics of new device compared to the predicate device.

The powdered vinyl patient examination gloves, Clear (Non-colored) non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 5250-06	Meets
Physical Properties	ASTM standard D 5250-06	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Amount	ASTM standard D 5250-06 and D6124-06	Meets <10mg/dm^2
Biocompatability	Primary Skin Irritation in rabbits	Pass Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig	Pass Not a Dermal sensitization

[(b)(1)] A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Powdered vinyl patient examination gloves , Clear (Non-colored) meet requirements per ASTM D5250-06, per ASTM D6124-06, per 21 CFR 800.20 and FDA recognition number 2-87: AAMI / ANSI / ISO 10993-10:2002.

[(b)(2)] A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

[(b)(3)] The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe,as effective, and performed as well or better than the legally marketed device identified in (a)(3).

It can be concluded that the Powdered Vinyl Patient Examination Gloves, Clear (Non-colored) meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL, meet labeling claims .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Zhang Jia Gang Fengyuan Plastic Products Company, Limited
C/O Mr. Chu Xiaoan
Official Correspondent
Room 1606 Building 1. Jianxiang Yuan
No. 209 Bei Si Huan Zhong Road
Haidian District
Beijing 100083, P.R. China

Re: K091662
Trade/Device Name: Powdered Vinyl patient Examination Gloves Clear (Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: May 30, 2009
Received: June 9, 2009

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: ZHANGJIAGANG FENGYUAN PLASTIC PRODUCTS CO.,LTD,

510(k) Number (if known): *

Device Name: Powdered Vinyl Patient Examination Gloves Clear (Non-colored)

Indications For Use:

Powdered vinyl patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091662